Lifeline Registry Update: Expansion to an Outcomes Registry

An overview of the progress to date and expanding initiatives for the near future.

FROM THE SVS/AVA OUTCOMES REGISTRY STEERING COMMITTEE

The Lifeline Registry of Endovascular Aneurysm Repair was established in 1998 by the Lifeline Foundation (now American Vascular Association Foundation), the nonprofit foundation of the Society for Vascular Surgery (SVS), as a mechanism to collect long-term safety, efficacy, and outcome data on endovascular graft recipients. Financial support for the Lifeline Registry is provided by Boston Scientific Corporation, Cook Incorporated, Edwards Lifesciences LLC, Endologix Incorporated, W. L. Gore & Associates, Guidant Corporation, Medtronic AVE, and TriVascular. The Registry database is managed and analyzed by New England Research Institutes, Inc., in Watertown, Massachusetts.

At the June 2004 Annual Conference of the Society for Vascular Surgery, Christopher Zarins, MD, on behalf of the Registry Publications Committee, presented the results of primary outcome measures (all-cause mortality, aneurysm-related mortality, rupture, surgical conversion) at 6 years.

DESIGN

The Registry contains data from the Guidant Ancure, Medtronic AneuRx, Gore Excluder, and Endologix PowerLink IDE abdominal aortic aneurysm (AAA) clinical trials with corresponding surgical controls, as well as postmarket commercial data from patients treated with Guidant Ancure, Medtronic AneuRx, Gore Excluder, Medtronic Talent (Investigator IDE), and Cook Zenith devices. With the coordination of Andrew Hill, MD, the Canadian Society for Vascular Surgery also participates in the registry by providing data on commercially available endovascular grafts. There are currently 2,908 endovascular graft patients and 334 surgical control patients in the Lifeline Registry database. This robust collection of safety, efficacy, and outcomes provides unbiased reporting of data.

> "Expansion to registry experiences, prototypes, and outcomes analyses beyond aneurysms, emphasizing CAS systems compared to CEA."

Because the basic tenet of the Lifeline Registry is to evaluate long-term safety and efficacy of endovascular grafts in general, all data analyses are performed by pooling results from multiple endovascular grafts. It is the position of the Registry that through pooling of results, the most reliable data regarding the utility of a new technology will be uncovered. Given the variability in the devices, including the experience of the surgeon, device improvements, device features, and patient compliance, device-specific analyses are not currently performed.

FINDINGS

Overall, patients receiving endovascular grafts were older and had more cardiac comorbidities compared to surgical controls (ie, open repair), but there was no difference in the primary endpoints of all-cause mortality, AAA death, or aneurysm rupture between the endovascular graft and surgical control groups up to 3 years. In general, analyses of endovascular graft data

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(***Lifeline Registry***, *continued from page 52)*

obtained from clinical trials (ie, manufacturer IDE) compared with commercially available grafts (ie, post-market surveillance) showed no statistically significant differences in either baseline characteristics or outcomes. Kaplan-Meier analysis of all endovascular graft recipients at 6 years revealed 99% freedom from rupture and 98% freedom from aneurysm-related death. Results of endovascular aneurysm repair are favorable even in elderly, higher-risk populations who are not appropriate candidates for surgery. Women have a higher risk of rupture and surgical conversion than men, but no difference in AAA death rate. It was concluded that endovascular grafts can be a safe, effective, and durable treatment of infrarenal AAAs. Appropriate patient selection and follow-up are necessary to optimize results. These data demonstrate safety, effectiveness, and long-term durability of endovascular grafts in the treatment of patients with infrarenal aneurysms.

> "Women have a higher risk of rupture and surgical conversion than men, but no difference in AAA death rate."

RECENT ACTIVITY

The Registry has published two reports regarding its design and content; however, the first detailed report of primary outcomes was submitted in December 2004 to the *Journal of Vascular Surgery* for publication. In addition to the impending publication, the Registry is working closely with the FDA and industry to provide a pool of surgical control patients, currently 334 patients, in a standard report format to model more efficient phase II clinical trials for premarketing approval.

Using the extensive experience with the Lifeline Registry, the SVS has the platform and the experience to establish and provide outcome analyses on thoracic aortic aneurysms (both endovascular graft recipients and open repair surgical controls). The Society is also developing a carotid stent/carotid endarterectomy registry to encompass both an extensive analysis of required postapproval studies and pending broad-label trials. In addition, the SVS is developing a program with the American College of Surgeons to initiate a carotid outcomes registry based on the National Surgical Quality Improvement Program (NSQIP) database. The effort to expand into a vascular outcomes registry is the new priority for the newly reorganized AVA/SVS. ■